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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,683	06/24/1999	GREGOR CEVC	500.1007	2670

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EXAMINER
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KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/07/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/284,683

Applicant(s)  
Cevc

Examiner  
Gollamudi Kishore

Art Unit  
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 3, 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-33 and 49-92 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-33 and 49-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

**The request for the extension of time, filing under 1.114 and the preliminary response all dated 7-3-03 are acknowledged.**

**Claims included in the prosecution are 22-33 and 49-92.**

#### ***Claim Rejections - 35 U.S.C. § 112***

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

- 2. Claims 22-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**It is unclear as to what applicant intends to convey by 'if there is a solubilizing point' in claim 22 (step e); if there is a solvent, then won't there be a solubilizing point? It is also unclear what the expression 'the reference particles are water' in step f is intended to convey. How can water form particles? The claim steps are very confusing.**

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The method in the independent claim 22 does not recite a concentration or lyophilization step; yet the dependent claim 33 recites 'a concentrate or lyophilisate'. Therefore, claim 33 is indefinite.

The examiner suggests a careful revision of all the claims.

*Claim Rejections - 35 U.S.C. § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 22-33 and 49-92 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 475 160 of record (English equivalent, US 6165,500).

EP discloses instant composition (transferosomes) containing a drug, amphiphilic lipids (such as PC and PG) and a surfactant (oleic acid) in instant amounts and a method of preparation ( see the entire document and the English equivalent). The Examples 32-39 show the amounts of the lipids and surfactant which appear to fall within the claimed limits. Although the reference does not explicitly recite the claimed steps such as selecting the lipids, adopting the composition by adjusting the amounts of the soluble component and adjusting the concentration of the lipid, since one cannot come up with specific

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amounts of the components as seen in example 32-39 of the reference without experimentation, the claimed steps are deemed to be implicit.

Applicant's arguments have been fully considered, but are found to be persuasive. Applicant argues that EP is very different and that it considers only one situation, namely, that the system defined has a solubilization point whereas in instant invention there are two possibilities. This argument is not found to be persuasive since as applicant himself argues instant invention allows two possibilities, one with the solubilization point and one without and the prior art teaches one of the possibilities. Applicant's arguments with regard to the amounts of surfactant are not persuasive since the examples 31-39 indicate the claimed amounts.

*Claim Rejections - 35 U.S.C. § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 22-33 and 49-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 475 160 cited above (English equivalent, US 6,165,500).

As pointed out above, EP teaches a composition containing a drug, amphiphilic lipids and a surfactant in instant amounts and a method of preparation. It is unclear

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whether the reference teaches all the instant functional parameters. In case they are different, in the absence of showing the criticality, they are deemed to be parameters manipulatable by an artisan to obtain the best possible results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again center around the differences in the mole percentages in the prior art and in instant invention. These arguments are not found to be persuasive since as pointed out above, prior art is suggestive of manipulations of the ratios between the lipid and the solubilizing agent and therefore, one of ordinary skill in the art would be motivated to manipulate its teachings with the expectation of obtaining the best possible product, i.e., transferosome.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**September 16, 2003**